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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,254	09/30/2003	Hikaru Matsuda	12289/3	2567

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EXAMINER	
VANIK, DAVID L	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,254	MATSUDA ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *14,15 and 18-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/26/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Applicants' response to the election/restriction requirement on 9/23/2005.

Election/Restrictions

Applicants' election of Claims 1-17 in the reply filed on 9/23/2005 is acknowledged. Response is also acknowledged of Applicants' election of the species "cells" and "accelerating the liquid drug." Since the "decreasing the liquid drug" species was not elected, Claims 14-15 are withdrawn from consideration. As such, Claims 1-13, 16-17 are pending in the instant application. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-13, 16-17 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13, 16-17 of copending Application No. 10/954639 ('639). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Like the instant application, '639 claim a method for injecting a liquid drug containing a biological material into a subject at a predetermined range of velocity (Claim 1 of '639). '639 also claim a method for injecting a liquid drug containing a biological material into a subject at an accelerated range (Claim 6 of '639). The velocity ranges, diameter of the injector, and biological materials are also the same in '639 and the instant claims 1-13, 16-17 (See Claims 2-5, 7-13, and 16-17 of '639).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As set forth in Claim 16, it is unclear what the phrase "prophylaxis of a heart" means. Interpreted literally, "prophylaxis of a heart" appears to mean "prevention" of a heart. The examiner fails to understand the meaning of the phrase "prophylaxis of a heart." As such, further clarification is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,139,529 ('529).

'529 disclose a dental anesthetic method comprising injecting an anesthetic solution (liquid drug containing a biological material) to a tissue at a predetermined rate of velocity (abstract, column 4, lines 20-61). Like the instant application, the liquid drug can be injected into a tissue at a rate of less than 10 ml/min (Claims 1-6 and column 4, line 44). Since the anesthetic is fully functional when injected into a patient, it is the examiner's position that the predetermined rate of velocity the injection maintains the activity of the anesthetic.

The claims are therefore anticipated by US Patent 6,139,529 ('529).

Claims 1-2, 6-7, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,647,851 ('851).

'851 disclose a method of injecting a medicine, specifically an anesthetic, to an individual at a predetermined rate of velocity (abstract, column 1, line 61 – column 2, line 14). Like the instant application, the medicine may also be accelerated at a

predetermined range (column 3, lines 5-21 and column 9, lines 43-47). Since the medicine is fully functional when injected into a patient, it is the examiner's position that the predetermined rate of velocity the injection maintains the activity of the anesthetic.

The claims are therefore anticipated by US Patent US 5,647,851 ('851).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/39624 ('624) in view of US 6,673,604 ('604).

'624 teach an apparatus for intra-cardiac drug delivery (abstract). The device can deliver a dose of a biological material, such as growth factor, at a determined range of velocity to the heart (abstract and Claim 45). According to '624, the therapeutic agent can be delivered to the heart in a manner that is responsive to physiological signals (Claim 45). On the basis of the physiological signals, it is the examiner's position that one of ordinary skill in the art would have the ability to modulate the rate of drug administration on the basis of the particular application. As such, it is the examiner's position that an ordinary practitioner would have the ability to accelerate or maintain the release of the drug on the basis of evolving physiological signals. It is also the examiner's position that an ordinary practitioner would be able to modify the tip tube of the to between 0.1mm to about 30 mm on the basis of the particular size of the heart or organ to be injected.

'624 does not teach a method of injected cells into an individual at a predetermined rate. However, '604 teach a method of injecting cells into a heart (abstract and Example 1). According to '604, it is advantageous to inject muscle cells into a heart because said muscle cells can aid in cardiac repair (abstract). Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a heart in a manner consistent with the disclosure of '624. Based on the teachings of '604, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to inject cells, in a manner consistent with the method advanced by '624, into a heart.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

11/18/2005

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500